

### REMARKS

Claims 20-23 and 25-30 are pending in the present application. Claims 20-23 and 25-30 have been rejected. The previous rejections have all been withdrawn; see pages 2-3 of the Office Action. However, new grounds of rejection have been made by the Examiner.

#### **(1) Rejection of claim 20 under 35 USC§102(b)**

The Examiner rejects claim 20 as being anticipated by Okuno et al. (Cancer Research 60, p2988-2995, June 1, 2000) under 35 USC 102(b). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested. The reasons for the traversal are explained below.

The Examiner indicates that in Okuno's literature ("Characterization of T-0128" (page 2989, right column)) there is a description of **"a liquid composition comprising T-0128 in a 0.2M phosphate buffer at pH 6.9 in water at a content of 4.5-5.5%w/w"**. However, this indication is clearly based on a misunderstanding on the part of the Examiner. Namely, in Okuno's literature there is no description of a liquid composition of T-0128, including the above disclosure.

In the part of the description indicated by the Examiner, it is only described that 0.2M phosphate buffer (pH 6.9) was used as a gel mobile phase in order to measure the molecular weight of T-0128. Specifically, in the part indicated by the Examiner, the description that "The content of T-2513 was 4.5-5.5%w/w" does not mean concentration in a solution. Rather, this means % by weight of T-2513 (drug) in one molecule of T-0128, as is clear from Fig. 1 of the reference. As explained above, such "a liquid composition comprising T-0128 in a 0.2M

phosphate buffer at pH 6.9 in water at a content of 4.5-5.5%w/w" as indicated by the Examiner is not described in the Okuno et al literature. Therefore, it is believed that the Examiner's position that claim 20 is anticipated by Okuno's literature should be withdrawn.

**(2) Rejection under 35 USC§103(a)**

**(i) Rejection of claim 22**

The Examiner rejects claim 22 on the ground that it would be obvious over Okuno's literature citation. However, it is the Applicant's position that, indeed, the claimed invention is not obvious to one skilled in the art. The reasons for this position are explained below.

As explained above, as in Okuno's literature, there is no description of "a liquid composition comprising T-0128 in a 0.2M phosphate buffer at pH6.9 in water at a content of 4.5-5.5%w/w", whatever the descriptions in other parts of Okuno's literature indicated by the Examiner are (page 2990, left column, the first paragraph and right paragraph, the second column). Okuno's literature does not constitute any basis to deny claim 22 for the reason that it would be obvious over the references.

**(ii) Rejection of claims 20, 22 and 25-28**

The Examiner rejects claims 20, 22 and 25-28 as being obvious over Okuno's literature in view of Harada's literature. Withdrawal of this rejection is requested.

As explained above, as with the Okuno literature, there is no description of "a liquid composition comprising T-0128 in a 0.2M phosphate buffer at pH6.9 in water at a content of 4.5-5.5%w/w". Thus, it is clear that none of the claims would be obvious over the references even if both references are combined in any way.

As explained above with reference to the Okuno literature, there is no such a description as "a liquid composition comprising T-0128 in a 0.2M phosphate buffer at pH6.9 in water at a content of 4.5-5.5%w/w". Thus, it is clear that none of the above claims would have been obvious over them even if the references are combined in any way.

**(iii) Rejection of claims 20-23 and 25-30**

The Examiner rejects claims 20-23 and 25-30 as being obvious over Okuno's literature in view of Harada's literature and further in view of Inoue et al. (WO99/46260) and USP 5,340,817.

As explained above, as in Okuno's literature, there is no description of a "a liquid composition comprising T-0128 in a 0.2M phosphate buffer at pH6.9 in water at a content of 4.5-5.5%w/w", and it is clear that none of the claims would be obvious over the cited references even if the references are combined in any way.

Finally, as also explained above, the Examiner rejects present claims 20-23 and 25-30 based on a description which is not present in Okuno's literature. Therefore, we believe that these rejections should be withdrawn and present claims 20-23 and 25-30 should be allowed.

In view of the Remarks presented herein, it is believed that the pending claims are allowable and that the remaining rejections should be withdrawn. In many places in the Office Action, the Examiner states that Okuno et al. "does not specifically disclose ..."—see, for example, page 5, fourth paragraph; page 6, fourth paragraph; and page 7, paragraph bridging pages 7-8 in the Office Action. Such hindsight with respect to the claims is not acceptable as a basis for rejection.

Favorable action is requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Raymond C. Stewart, Registration No. 21,066, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: April 16, 2010

Respectfully submitted,

By Raymond C. Stewart

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